REMARKS

Claims 1-4, 6, and 8-14 are pending in this application. Claims 5 and 7 are cancelled with out prejudice or disclaimer. Claims 6 and 8-14 are withdrawn. Withdrawn claim 6 is amended in accordance with MPEP 821.04(b). Claim 6 is amended to be dependent of claim 8, which falls under Restriction Group III, as set forth by the examiner. Therefore no new matter has been added. A first office action on the merits is awaited.

On pages 2-4 of the office action, the examiner considers that the application contains three separate and distinct inventions, directed to:

GROUP I: Claims 1-4, Drawn to the compound morphine-6-glucuronide hydrobromide and compositions containing said salt;

GROUP II: Claims 5-7 and 10-14, Drawn to a method of making M6G.HBr and of making a medicament wherein the medicament comprises M6G.HBr; and

GROUP III: Claims 8 and 9, Drawn to a method of treating pain or breathlessness in a subject comprising administering M6G.HBr.

The examiner states that the claims of Groups I-III do not relate to a single general inventive concept because they lack the same or corresponding "special technical features." The examiner asserted that the common special technical feature shared by these groups is the compound morphine-6-glucuronide hydrobromide and a well-known pharmaceutical compound morphine-6-glucuronide is disclosed by Cowie *et al.* (EP0816375). In particular, the examiner asserts that morphine-6-glucuronide hydrobromide is a salt of the well-known pharmaceutical compound, and that bromides are well-known pharmaceutically acceptable salts for amines like morphine-6-glucuronide.

Applicants respectfully disagree with the examiner and submit that Cowie *et al.* (EP0816375) disclosure relates to glycoconjugates of opiated substances. There is no disclosure or suggestion in this document to provide a hydrobromide salt of morphine-6-glucuronide, or that such salts may have advantageous properties. Accordingly, there is no teaching to the skilled person to make such salt.

The examiner comments that a finding of unexpected results is heavily dependent on the nature of the specific invention being claimed and cannot be generalized to any possible invention involving the compound. Again, the applicants disagree with the examiner and indicate that the instant invention provides the hydrobromide salt of morphine-6-glucuronide (M6G.HBr) that has unexpected properties. In particular, M6G.HBr is surprisingly stable compared to M6G base and other M6G salts (see page 1, paragraph 4 of the specification, for example). There is no suggestion to the skilled person in the cited reference to make a hydrobromide salt of M6G, nor any teaching that such a salt might have advantageous properties. Thus, the claimed compound (M6G.HBr) is novel, inventive and not obvious.

Therefore, the claimed hydrobromide salt (M6G.HBr) is a special technical feature shared by each of the inventions (claims of the Restriction Groups I, II and III) as identified by the examiner, and the inventions are linked so as to form a single general inventive concept.

Applicants further refer the examiner to the PCT rule 13.2 that:

> "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

As discussed above, since the claimed compound (M6G.HBr) is novel and inventive, claims drawn to the compound morphine-6-glucuronide hydrobromide salt and compositions containing the salt (Group I), claims drawn to a method of making M6G.HBr and of making a medicament comprising M6G.HBr (Group II), and claims drawn to a method of treating pain or breathlessness in a subject comprising administering M6G.HBr (Group III) have fulfilled the requirement of PCT § 13.2 Unity of Invention. Therefore, applicants request withdrawal of the restriction and rejoinder of the claims of Group II and III, as set forth by the examiner.

Respectfully submitted,

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